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07 February 2005

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Food and Drug Administration
Center for Devices and Radiological Health
Regulations Staff (HFZ-215)
1350 Piccard Drive
Rockville, Maryland 20857

Re: Reclassification Petition for the
Non-invasive Bone Growth Stimulator
Under Section 513(e) of the FDCA

Dear Sir or Madam:

Enclosed with this letter is a petition requesting that the Non-invasive Bone Growth Stimulator be reclassified from Class III to Class II in accordance with Section 513(e) of the Food, Drug and Cosmetic Act (FDCA), 21 CFR § 860.123 and 21 CFR § 860.130.

The Non-invasive Bone Growth Stimulator is a post-Amendments device; i.e., the Agency determined that this device did not fit within any pre-Amendments type of device. As a result, this type of device was automatically classified by Section 513(f)(1) of the FDCA into Class III, and no specific device within this type can be marketed unless it has received premarket approval, or unless this type of device is reclassified into Class I or II.

This petition presents evidence that the Non-invasive Bone Growth Stimulator does not conform to the criteria for Class III described in Section 513(a)(1)(C) of the FDCA, but conforms to the criteria described in 513(a)(1)(B) for Class II devices. This petition also demonstrates how the application of General and Special Controls, such as a proposed guidance document, conformance to safety standards, and compliance with the Quality System Regulation, will provide a reasonable assurance of device safety and effectiveness.

Thank you in advance for your prompt attention to this matter. If you have any questions regarding this petition, please contact me at (360) 891-7290.

Sincerely,

William Carroll/jp

William Carroll
Vice President, Research and Development

Enclosure

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